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Pesticide Fact Sheet Number 98: Methyl Bromide

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

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Pesticide Fact Sheet

Name of Chemical: Methyl Bromide
Reason for Issuance: Registration Standard
Date Issued: August 22, 1986
Fact Sheet Number: 98

1. Description of Chemical

Generic Name: Bromomethane

Common Name: Methyl Bromide

Trade Names Brom-O-Gas®; Celfume®; Dowfume®; Embafume®; Kayafume®; Meth-O Gas®; Terr-O-Gas 100®

EPA/OPP Pesticide Chemical Code: 053201

Chemical Abstracts Service (CAS) Number: 74-83-9

Year of Initial Registration 1961

Pesticide Type: Acaricide; Fungicide; Herbicide; Insecticide; Nematicide; Rodenticide

Chemical Family Halogenated Hydrocarbons

U.S. and Foreign Producers: Great Lakes Chemical Corporation; Ethyl Corporation; Ameribrom, Inc.

2. Use Patterns and Formulations

Application Sites: Agricultural crops; ornamentals; soil, manure, mulch and compost fumigation; stored commodities (both raw agricultural commodities and processed foods/feeds); greenhouses; homes; grain elevators; mills; ships and transportation vehicles.

Types of Formulations: Gaseous, liquid under pressure, or liquid.

Types and Methods of Application: Chisel application to field soil; gravity distribution for smaller bins; forced (recirculation) distribution systems; tarpaulin.

Application Rates: For stored product pests infesting raw agricultural commodities, dosage rates are between 2-6 lbs/1000 cu. ft. with exposure times ranging from 12-24 hours for nuts and grain and from 2-4 hours for other commodities; for processed foods, dosage rates are between 1-3 lbs/1000 cu. ft. with exposure times ranging from 12-24 hours; for soil fumigation uses, dosage rates are between 180-870 lbs/A depending on the type of application with exposure times ranging from 24-48 hours; for structural pest control, dosage rates are between 1-3 lbs/1000 cu. ft. with exposure times ranging from 2-24 hours for insects and 12-18 hours for mice and rats.

Usual Carriers: None

3. Science Findings

Although methyl bromide has been widely used for many years, its chronic toxicity has not been adequately characterized. Uncertainty also exists in the areas of dietary exposure, applicator exposure, and groundwater contamination.

Chemical Characteristics:

Physical State: Gaseous, liquid under pressure

Odor: Odorless

Boiling Point: 4°C

Melting Point: -94°C

Flash Point: Nonflammable

Unusual Handling Characteristics: Non corrosive to metal containers; however, traces of water or acid may lead to corrosion of application equipment

Toxicology Characteristics:

Acute Oral Toxicity: Toxicity Category II; LD_{50} in the rat is 214 mg/kg

Acute Inhalation Toxicity: Toxicity Category I based on human experience and use history; LD_{50} is 2700 ppm for a 30 minute exposure in the rat; in humans, 1,583 ppm (6.2 mg/l) was lethal to adults exposed for 10-20 hours while 7,890 ppm (30.9 mg/l) was lethal after 1 1/2 hours.

Primary Eye Irritation: Toxicity Category I; Corrosive

Primary Skin Irritation: Toxicity Category I; Corrosive

Major Route of Exposure: Inhalation

Problems which are known to have occurred with use of methyl bromide: In California, methyl bromide ranks seventh in terms of systemic poisonings, second in terms of number of people hospitalized and first in terms of number of days hospitalized for 1982-1985.

The chronic and subchronic toxicity data base is limited. A teratogenicity study in the rat and several mutagenicity studies are negative. Under the Data Call-In Program for Grain Fumigants, reproduction and oncogenicity studies were required. Preliminary results of these studies indicate that they are both negative. Mutagenicity, rabbit teratology, subchronic inhalation in the rat and rabbit, and chronic feeding studies in the rat and dog are required to complete the toxicology data base for methyl bromide.

Physiological and Biochemical Behavioral Characteristics: N/A

Environmental Characteristics:

Hydrolysis data indicate that methyl bromide breaks down at a rate of 1.4 mg/liter water/day at 25°C. Methyl bromide is not expected to run off fields to surface water because of application methods.

Ecological Characteristics:

Based on the registered patterns of use, no exposure to endangered species is expected.

Efficacy Review Results: N/A

Tolerance Assessments:

Tolerances are established at §180.123 of 40 CFR for residues of inorganic bromide (iBr) (calculated as Br) in or on a wide variety of agricultural commodities which have been fumigated with methyl bromide after harvest. Tolerances range from 5ppm - 240ppm, with the majority at 50ppm or less.

Tolerances are established at §180.199 of 40 CFR for residues of inorganic bromides (calculated as Br) in or on various raw agricultural commodities grown in soil fumigated with combinations of chloropicrin and methyl bromide.

Tolerances are established at §193.225 of 21 CFR for residues of inorganic bromides (calculated as Br) in or on milled fractions derived from cereal grains which have been fumigated with methyl bromide from all fumigation sources, including fumigation of grain-mill machinery, not to exceed 125 parts per million.

Tolerances are established at §193.230 of 21 CFR for residues of inorganic bromides (calculated as Br) in or on corn grits and cracked rice used in the production of fermented malt beverages which have been fumigated with methyl bromide. not to exceed 125 parts per million. Residues of inorganic bromides (calculated as Br) in the fermented malt beverage cannot exceed 25 parts per million.

Tolerances are established at §193.250 of 21 CFR for residues of inorganic bromide (calculated as Br) in or on the following processed food which have been fumigated with methyl bromide:

400 parts per million in or on dried eggs and processed herbs and spices.

325 parts per million in or on parmesan cheese and roquefort cheese.

250 parts per million in or on concentrated tomato products and dried figs.

125 parts per million in or on processed foods other than those listed above.

Tolerances are established at §561.260 of 21 CFR for residues of inorganic bromide (calculated as Br) in or on the following processed feed which have been fumigated with methyl bromide:

400 parts per million for residues in or on dog food.

125 parts per million for residues in or on milled fractions for animal feed from barley, corn, grain sorghum (milo), oats, rice, rye and wheat.

Data gaps exist for storage stability and the metabolism of methyl bromide in plant commodities fumigated postharvest. The requirements for animal metabolism data and livestock feeding studies are reserved pending the results of plant metabolism, storage stability, and plant residue data.

Pending submission of the requested plant metabolism data (and the conditionally required animal metabolism data), inorganic bromides and methyl bromide per se (MeBr per se) will tentatively be considered the only residues of concern resulting from both preplant soil and stored commodity fumigations. If the requested metabolism data and residue data on feed items so indicate, livestock metabolism and/or feeding studies involving iBr and MeBr per se may be required. Upon receipt of these studies, the Agency will determine the necessity and magnitude of tolerances in animal products for iBr, MeBr per se, and perhaps other metabolites of concern if found in metabolism studies.

None of the iBr tolerances in or on raw agricultural commodities (RACs) or processed products are supported due to the inadequacy of available data (40 CFR 180.123 and 180.199; 21 CFR 193.225, 193.250, and 561.260). In addition, data are required for each registered RAC and processed product depicting the residues of MeBr per se resulting from stored commodity fumigation (and possibly preplant soil fumigation). If both preplant and stored commodity fumigations are registered uses on a given commodity, then data are required depicting both iBr and MeBr per se residues resulting from the combination of the two types of treatment.

No crop group tolerances, as specified under 40 CFR 180.34(f), may be established at this time.

The TMRC for inorganic bromides is 25 mg/day based on a 1.5 kg diet. The ADI is 1.1 mg/kg/day (set by FDA); currently the TMRC accounts for 37.35 percent of the ADI.

4. Summary of Regulatory Position and Rationale

Methyl bromide is not being placed in the Special Review process at this time. Although the Agency is concerned about the acute toxicity risks associated with the use of methyl bromide, it believes that the precautionary labeling measures required by this standard, monitoring to establish safe levels for reentry to enclosed spaces and the addition of chloropicrin to formulations as a warning agent will significantly reduce these risks.

The Agency is requiring that chloropicrin at a concentration between 0.25% and 2.0% be present as a warning agent in all formulations, except those used for commodity fumigation. Since methyl bromide is odorless, the use of chloropicrin with its ability to cause painful iritation to the eyes, producing tearing and its disagreeable pungent odor at low concentrations will warn workers of methyl bromide exposure and will promote its safe use.

Methyl bromide products that are restricted according to 40 CFR 162.31 will continue to be restricted. Additionally, the Agency will propose to amend 40 CFR 162.31 to require restricted-use classification of all other product containers of methyl bromide. The restricted-use classification is necessary to protect users from the acute toxic effects of methyl bromide.

Because of the limitations of space on labels and the complexity of the precautions necessary to safely use methyl bromide, the Agency will require the development of application manuals by the manufacturers.

The Agency will continue to require that enclosed spaces fumigated with methyl bromide be aerated until the level of methyl bromide is below 5 ppm. This level was established under the Label Improvement Program for Fumigants, PR Notice 85-6, August 30, 1985, because the Agency was concerned about the possible inhalation exposure of workers.

Based on all available data, the Agency has determined that during soil fumigation the concentration of MeBr in the working area will not generally exceed 5 ppm as a time weighted average and will not require approved respiratory equipment to be worn. Such equipment is required to be available on the premises in case of a spill or leak.

The Agency will not impose a special label advisory statement for endangered species at this time because there is no expected exposure based on the registered patterns of use.

The Agency will require the submission of supporting data to support the current tolerances for mangoes, papayas, pomegranates, and cumin seed. There are no registered uses for these commodities, but the tolerances may be required for importation purposes. If the data are not developed, these tolerances may be revoked.

Due to the inadequency of available data, the Agency is requiring the submission of residue chemistry data to support all current inorganic bromide tolerances and to establish tolerances for methyl bromide per se.

Since none of the current methyl bromide tolerances are supported by data, no crop group tolerances, as specified under 40 CFR 180.34(f) may be established at this time. When data are received, crop grouping will be considered.

Since tolerances for methyl bromide per se are now being required, the Agency will propose to delete 40 CFR 180.3(c), the section which currently exempts the organic molecule from tolerances.

As soon as the required inorganic bromide data have been submitted, the Agency will consider deleting all existing paragraphs in the 21 and 40 CFR concerning inorganic bromide tolerances and replacing them with a single paragraph for raw agricultural commodities (40 CFR 180) and processed products (21 CFR 193 and 561).

Because of the residue and toxicology data gaps for methyl bromide, the Agency will not consider significant new food uses until the data are submitted.

While data gaps are being filled, currently registered manufacturing-use and end-use product containing methyl bromide may be sold, distributed, formulated, and used, subject to the requirements of the methyl bromide registration standard. The Agency does not normally cancel or withhold registration for previously registered use patterns simply because data are missing or inadequate. Data required under that Standard will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

Unique Warning Statements: Restricted-Use for retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification. Applicators must wear loose cotton long sleeve shirts and pants, shoes and socks that are cleaned after each wearing. Gloves and boots should not be worn, as methyl bromide is heavier than air and may be trapped inside and cause skin injury. Labeling for end-use products intended for structural, transportation, space, or commodity fumigation require the use of a self-contained breathing apparatus (SCBA) or combination air-supplied/SCBA respirator if the concentration in the working area exceeds 5 ppm (20 mg/m3). Labeling for end use products intended for outdoor (soil fumigation) uses require approved respiratory equipment to be available in case of emergency situations but do not require SCBA under normal conditions of use.

5. Summary of Major Data Gaps

Residue Chemistry:

Plant Metabolism: Due August 1987
Plant Residue Analytical Methods: Due February 1988
Storage Stability Data: Due February 1988
Magnitude of the Residue Studies: Due August 1989

Environmental Fate:

Photodegradation in Water: Due May 1987
Aerobic Soil: Currently under review
Anaerobic Soil: Currently under review
Leaching and Adsorption/Desorption: Currently under review
Field Dissipation Studies-Soil: Currently under review

Toxicology:

90-Day Inhalation-Rat: Due November 1987
90-Day Inhalation-Rabbit: Due November 1987
Chronic Toxicity-Rat (Gavage): Due October 1990
Chronic Toxicity-Dog (Gavage): Due October 1990
Oncogenicity-Rat (Inhalation): Due January 1987
Oncogenicity-Mouse (Inhalation): Due January 1987
Oncogenicity-Rat (Gavage): Due October 1990
Oncogenicity-Rat (Gavage): Due October 1990
Teratogenicity-Rabbit: Due November 1987
Reproduction-Rat (Inhalation): Currently under review
Reproduction-Rat (Gavage): Due November 1989
Mutagenicity: Due August 1987

Reentry:

Soil Dissipation: Due November 1988
Inhalation Exposure: Currently under review

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